

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US2006/006335

International filing date: 22 February 2006 (22.02.2006)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/731,316
Filing date: 28 October 2005 (28.10.2005)

Date of receipt at the International Bureau: 04 April 2006 (04.04.2006)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

March 27, 2006

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK
OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE.

APPLICATION NUMBER: 60/731,316**FILING DATE: *October 28, 2005*****RELATED PCT APPLICATION NUMBER: *PCT/US06/06335***

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY
APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS
CONVENTION, IS **US60/731,316**



Certified by

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EL900587427US

| INVENTOR(S) | | |
|--|------------------------|---|
| Given Name (first and middle [if any]) | Family Name or Surname | Residence (City and either State or Foreign Country) |
| MICHAEL | BOST | Long Valley, NJ |
| Additional inventors are being named on the <u>PAGE 2</u> separately numbered sheets attached hereto | | |
| TITLE OF THE INVENTION (500 characters max): A MULTI-LAYERED FILM FOR PACKAGING | | |

113262 U.S. PTO
60/731316

102805

| | | | |
|---|-----------|------------------------|--|
| Direct all correspondence to: | | CORRESPONDENCE ADDRESS | |
| <input checked="" type="checkbox"/> The address corresponding to Customer Number: | | 28484 | |
| OR | | | |
| <input type="checkbox"/> Firm or Individual Name | | | |
| Address | | | |
| City | State | Zip | |
| Country | Telephone | Fax | |

ENCLOSED APPLICATION PARTS (check all that apply)

| | |
|---|---|
| <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 | <input type="checkbox"/> CD(s), Number of CDs _____ |
| <input checked="" type="checkbox"/> Specification Number of Pages <u>42</u> | <input checked="" type="checkbox"/> Other (specify) <u>POSTCARD</u> |
| <input checked="" type="checkbox"/> Drawing(s) Number of Sheets <u>4</u> | |

Application Size Fee: If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

METHOD OF PAYMENT OF FILING FEES AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT

| | | |
|---|---|--|
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. | TOTAL FEE AMOUNT (\$) | |
| <input type="checkbox"/> A check or money order is enclosed to cover the filing fee and application size fee (if applicable). | 200.00 | |
| <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached | | |
| <input checked="" type="checkbox"/> The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: <u>23-3425</u> | A duplicative copy of this form is enclosed for fee processing. | |

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

 No. Yes, the name of the U.S. Government agency and the Government contract number are: _____SIGNATURE Fernando A. BorregoDate 10/28/05TYPED or PRINTED NAME Fernando A. BorregoREGISTRATION NO. 34,780

(if appropriate)

TELEPHONE 734-324-7196Docket Number 12307**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PROVISIONAL APPLICATION COVER SHEET
Additional Page

PTO/SB/16 (12-04)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| First Named Inventor | MICHAEL BOST | Docket Number | 12307 |
|--|-------------------|---|-------|
| INVENTOR(S)/APPLICANT(S) | | | |
| Given Name (first and middle [if any]) | Family or Surname | Residence (City and either State or Foreign Country) | |
| JEFFREY P. | VIOLA | MANALAPAN, NJ | |
| JENNIFER R. | STEWART | DEARBORN, MI | |

Number 2 of 2

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

A MULTI-LAYERED FILM FOR PACKAGING**FIELD OF THE INVENTION**

[0001] The present invention generally relates to a film and packaging utilizing the film. More specifically, the present invention relates to a multi-layered film used to form a blister for a pharmaceutical package, and including first and third layers including styrene butadiene copolymer and a second layer including a cyclic olefin.

DESCRIPTION OF THE RELATED ART

[0002] Various films have been used with packages as dust and/or moisture barriers. More specifically, films have been investigated for use with pharmaceutical packages to form blisters to seal a pharmaceutical product within the pharmaceutical packages. The films investigated for use with the pharmaceutical packages typically include polymers that are formed from halogenated molecules such as polyvinyl chloride (PVC), polyvinylidene chloride (PvDC), and/or fluoropolymers. Although effective as dust and/or moisture barriers, the films formed from such halogenated molecules create environmental hazards upon manufacture. Upon manufacture or disposal of these films, some of the halogenated molecules are released into the environment in a gaseous form and contribute to environmental pollution.

[0003] Typically, the films that are used solely as dust barriers include a monolayer sheet including only PVC. These films typically do not include any additional polymer layers due to increased production costs that accompany the use of the additional polymers. These films also cannot be used as effective moisture barriers because PVC permits high levels of moisture to penetrate the film. Therefore, PVC is unsuitable for use alone in applications which require moisture protection, such as for some pharmaceutical applications.

[0004] Successful attempts have been made to overcome issues of moisture protection in films. These attempts include use of halogens and fluoropolymers in films that also include PVC and PvDC. The halogens and fluoropolymers typically include fluorine and polychlorotrifluoroethylene. Use of the halogens and fluoropolymers allows the films to provide adequate moisture protection and to be used as moisture barriers. However, like the films that include only PVC, use of the halogens and fluoropolymers is also associated with environmental pollution. Therefore, use of films including halogens and fluoropolymers is also not preferred.

[0005] A film including fluoropolymers that is representative of a film that is an effective moisture barrier is specifically disclosed in U.S. Patent Application Publication No. 2003/0203141 to Blum et al. The '141 publication uses a film including a first adhesive layer including a styrene butadiene copolymer, a base, an outermost layer including cyclic olefin copolymers, and a fluoropolymer in an outer layer of the film. The '141 publication does not use the styrene butadiene copolymer in the outermost layer of the film. Rather, the '141 publication uses a fluoropolymer in the outermost layer of the film. As a result, the film used in the '141 publication is associated with environmental concerns that accompany manufacture of the film and is not suitable for use. The '141 publication also uses the cyclic olefin copolymers in the outer layer of the film. It is known that the cyclic olefin copolymers are subject to degradation if contacted with oils, organic and alkaline solvents, and heat. Because of this degradation, the outer layer of the film of the '141 publication is subject to deterioration and poor performance.

[0006] Although the films formed from halogenated molecules are effective dust and/or moisture barriers, there remains an opportunity for a film to be formed from non-halogenated molecules that is resistant to degradation when contacted with oils, organic and alkaline solvents, and heat, and that has superior optical properties. Preferably, the film is also durable, can be efficiently

processed and is thermoformable at low temperatures, has a pleasing tactile feel, and is an effective dust and/or moisture barrier, thus reducing environmental hazards associated with halogenated molecules.

SUMMARY OF THE INVENTION AND ADVANTAGES

[0007] The present invention provides a film that includes first, second, and third layers. The first layer includes a styrene butadiene copolymer. The second layer is disposed on the first layer and includes a cyclic olefin. The third layer is disposed on the second layer as an outermost layer of the film. The third layer, like the first layer, includes styrene butadiene copolymer. The first and the third layers are substantially free of the cyclic olefin and the second layer is substantially free of the styrene butadiene copolymer.

[0008] The present invention also provides a pharmaceutical package. The pharmaceutical package includes a base layer, a sealant layer, and a blister. The sealant layer is disposed on the base layer and the blister is disposed on the sealant layer. The blister is formed from the film described above.

[0009] The present invention further provides a method of making the film. The method includes the step of forming a first layer including styrene butadiene copolymer. The method also includes the step of forming a second layer, including a cyclic olefin, on the first layer. The method further includes forming a third layer of the film including styrene butadiene copolymer, on the second layer, as an outermost layer of the film. The first and third layers are substantially free of the cyclic olefin and the second layer is substantially free of styrene butadiene copolymer.

[0010] The film of the present invention can be used in packaging as an effective dust and/or moisture barrier. Using styrene butadiene copolymer in the first and third layers of the film allows the film to be substantially transparent, have superior optical properties, and be impact

resistant and durable. Using the styrene butadiene copolymer also allows the film to be efficiently processed, have a pleasing tactile feel, and be thermoformable at low temperatures resulting in a low cost of producing the film. The film provides a 35% film yield advantage compared to competitive halogen-containing films due to a low density of the styrene butadiene copolymer. A higher quantity of the film of the subject invention can be purchased at the same weight as a comparative film because of the low density of the styrene butadiene copolymer.

[0011] Although free of halogens, the film of the present invention, when used in packaging, substantially prevents moisture from entering the packaging. Furthermore, because the film is free of halogens, the film also reduces potential environmental hazards associated with manufacturing and disposal of films including halogens. The film also is resistant to degradation when contacted with oils, organic and alkaline solvents, or heat, because the cyclic olefin of the second layer is sandwiched between the first and third layers including styrene butadiene copolymer.

[0012] The pharmaceutical package of the present invention effectively protects the pharmaceutical product from dust and/or moisture due to incorporation of the film of the present invention into the blister of the pharmaceutical package. Because the pharmaceutical package includes the film that is free of the halogens, the pharmaceutical package, like the film, can be manufactured without the environmental hazards associated with the halogens. Also, because the film is resistant to degradation when contacted with oils or organic solvents, the pharmaceutical package can be handled by consumers without breaking down.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0013] Other advantages of the present invention will be readily appreciated, as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

[0014] Figure 1 is a cross-sectional view of a first embodiment of the film of the present invention;

[0015] Figure 2 is a cross-sectional view of a second embodiment of the film of the present invention;

[0016] Figure 3 is a cross-sectional view of a third embodiment of the film of the present invention;

[0017] Figure 4 is a cross-sectional view of a fourth embodiment of the film of the present invention;

[0018] Figure 5 is a cross-sectional view of a first embodiment of the pharmaceutical package of the present invention;

[0019] Figure 6 is a cross-sectional view of a second embodiment of the pharmaceutical package of the present invention;

[0020] Figure 7 is a cross-sectional view of a third embodiment of the pharmaceutical package of the present invention;

[0021] Figure 8 is a cross-sectional view of a fourth embodiment of the pharmaceutical package of the present invention; and

[0022] Figure 9 is a cross-sectional view of a fifth embodiment of the pharmaceutical package of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0023] A film (20), according to the present invention, can be used in industrial production of a wide variety of packages to seal a content of the packages and protect the content from dust and/or moisture. Preferably, the film (20) is thermoformable and substantially free of halogens such that the film (20) can be used in packages where halogen-containing films are not desirable such as in a pharmaceutical package (22), described in greater detail below. The film preferably has less than 5,000, more preferably less than 900, and most preferably less than 100, parts of the halogens per one million parts of the film (20).

[0024] The film (20) of the present invention includes three layers including first, second, and third layers (24, 26, 28), as shown in Figures 1 through 4. Specifically, the first layer (24) includes a styrene butadiene copolymer, described in greater detail below. The first layer (24) also is substantially free of a cyclic olefin. The first layer (24) preferably has less than 10,000, more preferably less than 5,000, and even more preferably less than 1,000, parts of the cyclic olefin per one million parts of the first layer (24). Most preferably, the first layer (24) is totally free of the cyclic olefin.

[0025] It is also contemplated that the first layer may be of any thickness. However, the first layer (24) preferably has a thickness of from 0.5 to 12, more preferably of from 1 to 8, and most preferably of from 1 to 6, mils. The thickness of the first layer (24) contributes to both a light transmission and a haze of the film (20). Accordingly, the styrene butadiene copolymer allows the film (20) to have a high light transmission and a low haze, both of which contribute to a high transparency of the film (20), which is desirable.

[0026] A measurement of light transmission includes a measurement of an amount of light that passes through the film (20). An increase in the amount of light that passes through the film (20)

increases the transparency of the film (20). Preferably, the film (20) has a light transmission of from 88 to 93, and most preferably of from 90 to 93, percent, as determined by ASTM D-1003.

[0027] A measurement of the haze of the film (20) includes a measurement of the scattering of light as it passes through the film (20). A high haze clouds the film (20), which is not desirable. A decrease in the scattering of light as it passes through the film (20) indicates a low haze of the film (20) and a low cloudiness, which is desirable. The film (20) preferably has a haze of less than 9, more preferably of from 2 to 6, and most preferably of from 2 to 4, percent, as determined by ASTM D-1003.

[0028] Referring now to the first layer (24) first introduced above, the first layer (24) includes the styrene butadiene copolymer. The styrene butadiene copolymer preferably includes a reaction product of a styrene monomer polymerized with a butadiene. It is contemplated that the styrene butadiene copolymer may include a styrene butadiene block copolymer. It is to be understood that the terminology "block copolymer" refers to the styrene butadiene copolymer including repeating sequences of two or more distinct units, such as a styrene monomer. Typically, the styrene butadiene copolymer includes at least 50 weight percent of styrene, from 5 to 50 weight percent of the butadiene, and up to 10 weight percent of additional polymers. More typically, the styrene butadiene copolymer includes of from 60 to 90 and most typically of from 70 to 80, parts by weight of styrene per 100 parts by weight of the styrene butadiene copolymer. Also, the styrene butadiene copolymer more typically includes of from 10 to 40 and most typically of from 20 to 30, parts by weight of the butadiene per 100 parts by weight of the styrene butadiene copolymer. Most preferably, the butadiene includes 1,3-butadiene. However, any butadiene known in the art may be included.

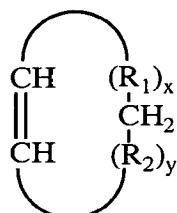
[0029] The styrene butadiene copolymer preferably has a melt flow rate of from 5 to 20, more preferably of from 8 to 17, and most preferably of from 10 to 15, g/10 minutes at 200°C/5 kg, as determined by ASTM D-1238. The melt flow rate is a measurement of a rate of extrusion of a molten styrene butadiene copolymer through a die of a specified length and diameter under prescribed conditions of temperature, load, and piston position in a barrel as a timed measurement is made. The styrene butadiene copolymer also preferably has a Vicat Softening Temperature of from 55 to 100, more preferably of from 60 to 95, and most preferably of from 65 to 90, °C, at 120°C/hr, 10N, as determined by ASTM D-1525.

[0030] Styrene butadiene copolymers are typically synthesized using anionic polymerization techniques including use of an alkylmetallic initiator and a coupling agent. Most typically, the alkylmetallic initiator includes an alkylolithium initiator and the coupling agent includes, but is not limited to, alcohols, organohalogens, esters, chlorosilanes, divinylbenzene, and combinations thereof. Examples of typical styrene butadiene copolymers and methods of synthesis are described in U.S. Pat. No. 4,086,298, incorporated herein by reference.

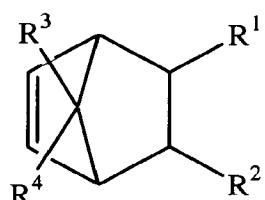
[0031] The preferred styrene butadiene copolymer used in the present invention is commercially available from BASF Corporation under the trade name of Styrolux®. Preferred examples of the styrene butadiene copolymer include Styrolux® 684D, Styrolux® 3G33, Styrolux® 3G55, and Styrolux® 656C. Styrene butadiene copolymers such as Styrolux® 684D, Styrolux® 3G33, Styrolux® 3G55, and Styrolux® 656C offer desirable properties such as high transparency, brilliance and impact resistance. However, other styrene butadiene copolymers are also commercially available from Shell Chemicals of Houston, TX and Asahi Chemical Ltd. of Kowloon, Hong Kong, under the trade names of Kraton®, and Asaflex®, respectively. Those

skilled in the art will choose a suitable styrene butadiene copolymer based on desirable properties, economics and suitability.

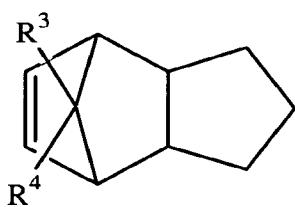
[0032] Referring now to the second layer (26) of the film (20) initially introduced above, the second layer, i.e., a core, is disposed on the first layer (24) which, in the context of the present invention, does not have to be in direct contact with the first layer (24). However, it is contemplated that the second layer (26) may be disposed in contact with the first layer (24). The second layer (26) includes the cyclic olefin. In one embodiment of the present invention, the cyclic olefin preferably includes the general structure:



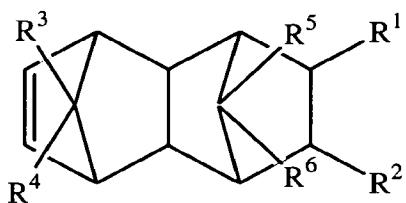
wherein each of R₁ and R₂ independently include one of a hydrogen and a hydrocarbon, and x and y independently include an integer less than or equal to 10. In another embodiment of the present invention the cyclic olefin includes at least one pendant organic group. The pendant organic group preferably includes, but is not limited to, alcohols, amines, carbonyls, ethers, hydrocarbons, nitriles, sulfides, and combinations thereof. Further, in another embodiment of the present invention, the cyclic olefin is selected from one of the general structures:



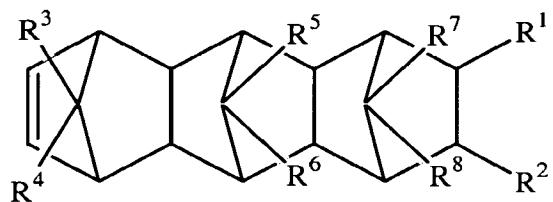
(I),



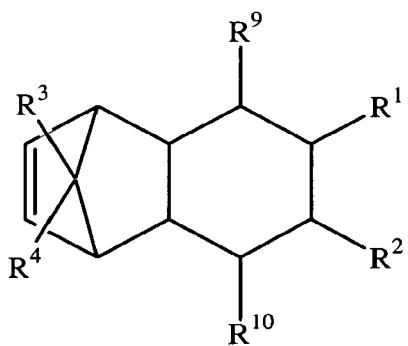
(II),



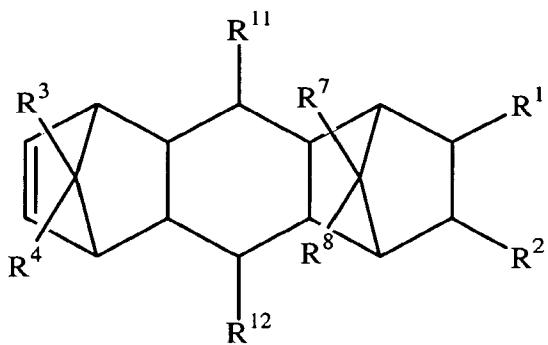
(III),



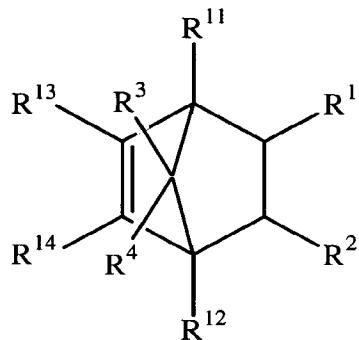
(IV),



(V),



(VI),



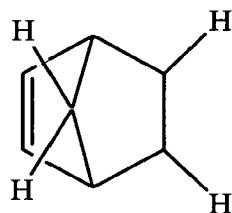
(VII),



(VIII),

wherein each of R¹ through R¹⁴ independently include one of an aryl group, an alkyl group, a halogen, a hydrogen, and any compound including combinations thereof and n includes an integer less than or equal to 10. It is to be understood that each of R¹ through R¹⁴ may be the same or may be different. Preferably, if one of R¹ through R¹⁴ includes the aryl group, the aryl group includes of from 6 to 20 carbon atoms. Also, if one of R¹ through R¹⁴ includes the alkyl group, the alkyl group preferably includes of from 1 to 20 carbon atoms. Examples of suitable cyclic olefins include, but are not limited to, norbornene, dimethyl-octahydro-naphthalene, cyclopentene, (5-methyl) norbornene, and combinations thereof. Most preferably, the cyclic

olefin includes norbornene. For descriptive purposes only, a chemical structure of norbornene is illustrated below.



[0033] Alternatively, the cyclic olefin may include a cyclic olefin copolymer. Cyclic olefin copolymers typically include mono or poly-unsaturated ring systems including, but not limited to, monocyclic alkenes, bicyclic alkenes, tricyclic alkenes, tetracyclic alkenes, polycyclic alkenes, and combinations thereof. A suitable example of a monocyclic alkene includes cyclopropene. The ring systems may be unsubstituted, monosubstituted, or polysubstituted and may include one of the cyclic olefins described above, and combinations thereof. Most preferably, the cyclic olefin copolymer includes an interaction product of the cyclic olefin and a cross-linker. The cross-linker preferably is a molecule that is unlike the cyclic olefin. If the second layer (26) of the film (20) includes the cyclic olefin copolymer and the cross-linker, the cross-linker is preferably selected from the group of alkanes, alkenes, alkynes, and combinations thereof. It is contemplated that alkenes may include acyclic olefin monomers including, but not limited to, ethylene, propylene, butylene, and combinations thereof. It is also contemplated that any acyclic olefin monomer known in the art may be used in the present invention.

[0034] Preferably, the cyclic olefin copolymer includes norbornene and ethylene. If the cyclic olefin copolymer includes norbornene, the norbornene is preferably included in an amount of from 10 to 70 and more preferably of from 25 to 45, mole percent. If the cyclic olefin copolymer includes ethylene, preferably the ethylene is included in an amount of from 30 to 90 and more

preferably of from 55 to 75, mole percent. However, it is contemplated that the norbornene and the ethylene may be included in any amount.

[0035] Preferred examples of cyclic olefin copolymers are commercially available from Ticona of Florence, KY, under the trade name of Topas®, from Zeon Chemicals of Louisville K.Y., under the trade name of Zeonex®, from JSR Corporation of Tokyo, Japan, under the trade name of Arton®, and from Mitsui Petrochemical Industries of Tokyo, Japan. Most preferably, the cyclic olefin copolymer includes Topas® 8007F-04 which includes approximately 36 mole percent norbornene and a balance of ethylene.

[0036] The cyclic olefin copolymer may be synthesized by any method known in the art. Typically, the cyclic olefin copolymer is synthesized using transition metal catalysts including, but not limited to, metallocene catalysts. Examples of cyclic olefin copolymers that may be used in the present invention are described in U.S. Pat. Nos. 5,218,049, 5,783,273, and 6,068,936, which are incorporated herein by reference.

[0037] The film (20) also includes the third layer (28), as first introduced above. The third layer (28) is like the first layer (24) in composition because the third layer (28) includes the styrene butadiene copolymer and is substantially free of the cyclic olefin. However, the third layer (28) is unlike the first layer (24) in function because the third layer (28) is disposed on the second layer (26) as an outermost layer of the film (20) and protects the second layer (26) from degradation, discussed in greater detail below. The third layer (28) preferably has a thickness of from 0.5 to 12, more preferably of from 1 to 8, and most preferably of from 1 to 6, mils. The third layer (28) preferably contributes to the film (20) having a pleasing tactile feel.

[0038] The third layer (28) is disposed on the second layer (26) as the outermost layer of the film (20) to sandwich the second layer (26) between the first and third layers (24, 28). However, the

third layer (28) may be disposed in contact with the second layer (26). The first and the third layers (24, 28) sandwich the second layer (26) because the cyclic olefin included in the second layer (26) is subject to degradation if contacted with any oils or any organic solvents. However, the styrene butadiene copolymer included in the first and third layers (24, 28) is resistant to degradation if contacted with oils or organic solvents. Therefore, the sandwiching of the second layer (26) between the first and third layers (24, 28) is desirable to minimize degradation of the cyclic olefin and the second layer (26).

[0039] The film (20) may also include an intermediate layer (30) disposed between the first and second layers (24, 26), and/or between the second and third layers (26, 28) as shown in Figures 2 through 4. If included, the intermediate layer (30) may include, but is not limited to, nylons, ethyl vinyl alcohol, polyolefins including, but not limited to polyethylene and polypropylene, polyester, paper, and combinations thereof. The film (20) may also include a second intermediate layer (32) disposed between the second and third layers (26, 28), as shown in Figure 4. If the second intermediate layer (32) is included, the second intermediate layer (32) is the same as the intermediate layer (30).

[0040] In the present invention, the second layer (26) is sandwiched between the first layer (24) and the third layer (28) which gives rise to the aforementioned advantages. Also, in the present invention, preferably there is no tie layer present between any of the layers (24, 26, 28, 30, 32) of the film (20) because the layers (24, 26, 28, 30, 32) adhere effectively to each other. However, in scenarios where certain intermediate layers (30, 32) are utilized, tie layers may be necessary. If the film (20) does not have any tie layers, the film (20) can be manufactured at a lower cost and with fewer raw materials.

[0041] The film (20) also preferably has a peel strength of greater than 0.5, more preferably of greater than 1.0, and most preferably of greater than 1.5, lbs_f/in², as determined by ASTM D-903. A measurement of peel strength is a measurement of a strength required to pull apart a bonded surface, i.e., pull apart the first, second, and third layers (24, 26, 28) of the film (20) of the present invention. The measurement of peel strength of greater than 0.5 lbs_f/in² exhibited by the film (20) is desirable because the measurement indicates that the first, second, and third layers (24, 26, 28) of the film (20) are not easily pulled apart.

[0042] The second layer (26) is substantially free of the styrene butadiene copolymer and preferably has less than 10,000, more preferably less than 5,000, and even more preferably less than 1,000, parts of the styrene butadiene copolymer per one million parts of the second layer (26). Most preferably, the second layer (26) is totally free of the styrene butadiene copolymer. The second layer (26) also preferably has a thickness of from 1 to 10, more preferably of from 3 to 8, and most preferably of from 5 to 10, mils. The thickness of the second layer (26) contributes, along with the cyclic olefin itself, to an effectiveness of the film (20) in preventing moisture from passing through the film (20) and to the film having a low water vapor transmission rate. This is especially important in certain packaging applications such as in pharmaceutical packages where the product may be sensitive to moisture. It is contemplated that the second layer (26) may be of any thickness. However, the second layer (26) is preferably about four, and more preferably about six, times thicker than the first layer (24) and the third layer (28) individually.

[0043] A measurement of the water vapor transmission rate of the film (20) includes a measurement of an amount of water vapor that passes through a barrier material, i.e., the film (20), over 24 hours. Preferably, the film (20) has a water vapor transmission rate of from 0.20 to

5.00, more preferably of from 0.20 to 3.00, and most preferably of from 0.20 to 0.50, g/m²/24 hrs, as determined by ASTM F-1249.

[0044] Further, the film (20) preferably has a density of from 0.95 to 1.05, more preferably of from 0.98 to 1.03, and most preferably of from 1.00 to 1.02, g/cm³. Due to a low density of the film, the film provides a 35% film advantage compared to competitive halogen-containing films. The low density of the film can be attributed to the styrene butadiene copolymer that is included in the first and third layers (24, 28) of the film (20) and the cyclic olefin, that is included in the second layer (26) of the film (20). A higher quantity of the film (20) of the subject invention can be purchased at the same weight as a comparative film because of the low density of the styrene butadiene copolymer.

[0045] The present invention also provides a method of forming the film (20). The method includes the step of forming the first layer (24) including the styrene butadiene copolymer and the step of forming the second layer (26) including the cyclic olefin, on the first layer (24). The method also includes forming the third layer (28) including the styrene butadiene copolymer, on the second layer, as the outermost layer of the film (20), wherein the first and third layers (24, 28) are substantially free of the cyclic olefin and the second layer (26) is substantially free of the styrene butadiene copolymer.

[0046] Preferably, to form the first, second, and third layers (24, 26, 28), the styrene butadiene copolymer and cyclic olefin are introduced into an extruder which may be a single screw extruder. Most preferably, the styrene butadiene copolymer and the cyclic olefin are introduced into two in-feed hoppers of a first and a second extruder, a first extruder handling the styrene butadiene copolymer for the first and third layers (24, 28) and a second extruder handling the

cyclic olefin for the second layer (26). The first and the second extruders preferably melt and plasticize the styrene butadiene copolymer and the cyclic olefin, respectively.

[0047] Preferably, the step of forming the first layer (24) includes extruding the first layer (24). Also, preferably, the step of forming the second layer (26) includes extruding the second layer (26). Further, the step of forming the third layer (28) preferably includes extruding the third layer (28). Most preferably, the first, second, and third layers (24, 26, 28) are simultaneously extruded. However, it is also contemplated that the first, second, and third layers (24, 26, 28) may be extruded in any order and at different times. The first, second, and third layers (24, 26, 28) are preferably co-extruded such that there is no blending of the first, second, and third layers (24, 26, 28). If the first, second, and third layers (24, 26, 28) were blended in any manner in this embodiment, the film (20) may exhibit undesirable properties such as shrinkage and a lack of moisture prevention.

[0048] Most preferably, the first and the second extruders form two separate streams of the styrene butadiene copolymer and the cyclic olefin, respectively. Preferably, the first and second extruders include a temperature zone. However, the first and second extruders may include more than one temperature zone. Although the temperature zone may be heated to any temperature, the temperature zone of the first and second extruders is preferably heated to a temperature from 175 to 220°C.

[0049] The streams from the first and second extruders are preferably fed into a single manifold extrusion die or a multi manifold co-extrusion die to form the first, second, and third layers (24, 26, 28) of the film (20). While in the co-extrusion die, the first, second, and third layers (24, 26, 28) are preferably juxtaposed and combined, and emerge from the co-extrusion die as the film

(20) of the present invention. However, it is also contemplated that film (20) can be formed using a single manifold extrusion die utilizing feedblock technology.

[0050] It is further contemplated that the first, second, and third layers (24, 26, 28) may be melt-bonded together. Melt-bonding includes directly applying a subject film layer to an object film layer wherein both the subject and object film layers are in a partially softened or molten form. A suitable melt-bonding technique includes lamination techniques known in the art.

[0051] After exiting the die, the film (20) is preferably cast onto and passed around a first controlled temperature casting roll. The film (20) is then preferably passed onto a second controlled temperature casting roll, which is normally cooler than the first controlled temperature casting roll. The first and second controlled temperature casting rolls largely control the rate of cooling of the film (20) after it exits the co-extrusion die. Additional controlled temperature casting rolls may also be employed. Although the film (20) may be formed by co-extrusion, it is contemplated that the film (20) may be formed by any method known in the art

[0052] With particular reference to Figures 5 through 9, the pharmaceutical package (22), according to preferred embodiments of the present invention, will now be described in greater detail. As first introduced above, the film (20) of the present invention can be used to form a blister (38) in the pharmaceutical package (22) and seal the content of the pharmaceutical package (22) to protect the content from dust and/or moisture.

[0053] The pharmaceutical package (22) includes a base layer (34) that provides a base for the pharmaceutical package (22). The base layer (34), also known as a lidding layer, includes a material selected from the group of aluminum, paper, cardboard, wood, glass, fabric, fibers, polyester, and combinations thereof. Preferably, the base layer includes aluminum. Generally, if aluminum is included in the base layer (34), the aluminum may be hard aluminum, soft

aluminum, combined with paper, combined with nylon, and/or combined with paper, nylon, and polyester.

[0054] With continued reference to Figures 5 through 9, the pharmaceutical package (22) also includes a sealant layer (36) disposed on the base layer (34) that preferably acts as an adhesive between the base layer (34) and the blister (38). In the context of the present invention, the sealant layer (36) does not have to be in direct contact with the base layer (34). However, it is contemplated that the sealant layer (36) may be disposed in contact with the base layer (34).

[0055] The sealant layer (36) preferably is chemically compatible with both the base layer (34) and any other layers disposed on the sealant layer (36) to ensure maximum adhesion between the layers of the pharmaceutical package (22). The sealant layer (36) may include, but is not limited to, modified polyolefins, copolymers of alkynes, styrenes, compounds selected from the group of acrylic acid, alkyl acrylic acid, acrylates, and alkyl acrylates, and combinations thereof.

[0056] The modified polyolefins suitable for use in the sealant layer (36) may be prepared from olefins including homopolymers or copolymers of an α -olefins having from 2 to 40 carbons such as ethylene, propylene, butene-1, pentene-1, hexene-1,4-methylpentene-1, octene-1, and combinations thereof. One suitable example of the modified polyolefin that may be used in the sealant layer (36) includes a functionalized olefin with at least one functional moiety.

[0057] Examples of suitable functional moieties include, but are not limited to, unsaturated carboxylic acids, unsaturated carboxylic acid anhydrides, amines, epoxies, and combinations thereof. Unsaturated carboxylic acids and anhydrides that may be used in the functional olefin include, but are not limited to, maleic acid and anhydride, fumaric acid and anhydride, crotonic acid and anhydride, citraconic acid and anhydride, itaconic acid and anhydride, and combinations thereof. Suitable amines that may be used in the functional olefin include, but are

not limited to, aliphatic or aromatic amines, primary, secondary and tertiary amines, such as 2,4,6-tribromoaniline, methylamine, ethylamine, propylamine, dimethylamine, N-methylaniline, ethylmethylamine, 2-(N-methylamine)heptane, sec-butyldimethylamine, N-ethyl-N-methylaniline, trimethylamine, N,N-dimethylaniline, and combinations thereof. Suitable epoxies that may be used in the functional olefin include, but are not limited to, those having from 2 to 20 carbon atoms. Those skilled in the art will choose a suitable sealant layer (36) based on desirable properties, economics, and availability.

[0058] With continued reference to Figures 5 through 9, the pharmaceutical package (22) also includes the blister (38) disposed on the sealant layer (36) and formed from the film (20) of the present invention. In the context of the present invention, the blister (38) does not have to be in direct contact with the sealant layer (36). However, it is contemplated that the blister (38) may be disposed in contact with the sealant layer (36).

[0059] The blister (38) may be shaped using techniques that are well known in the art such as thermoforming. Typically, thermoforming includes an automatic high speed positioning of a sheet or film having an accurately controlled temperature into a pneumatically actuated forming station whereby a shape of the sheet or film is defined by a mold. The sheet or film, after positioned, may be trimmed or cut, as is known in the art. The thermoforming may utilize a variety of techniques including, but not limited to, use of a drape, vacuum, pressure, matched die, billow drape, vacuum snap-back, billow vacuum, plug assist vacuum, reverse draw with plug assist, trapped sheet, slip, diaphragm, twin-sheet cut sheet, and combinations thereof. The thermoforming may also utilize a freeblowing technique, a pressure bubble immersion technique, a twin-sheet roll-fed technique, a pillow-forming technique, a blow-molding technique, an extrusion blow-molding technique, and combinations thereof. Specifically, blow-molding

includes expanding a heated parison against surfaces of a mold using compressed gasses. It is also contemplated that multiple blisters (38) may be formed simultaneously using any of the aforementioned techniques, any technique known in the art, and combinations thereof.

[0060] The blister (38) is preferably molded from the film (20) of the present invention such that the blister (38) has an outer surface, an inner surface, and a cavity. The blister (38) may be of any desired shape. Preferably, the blister (38) is formed in a rectangular or hemispherical shape. In Figures 5-9, the blister (38) is shown with the layers (24, 26, 28) of the film. However, it is to be understood that in all Figures and in all embodiments of the present invention, the blister (38) may include the first and second intermediate layers (30, 32) of the film (20). After the blister (38) is shaped, a pharmaceutical product (48) such as a tablet or capsule is preferably disposed within the blister (38), i.e. within the cavity, and the blister (38) is preferably sealed. However, it is also contemplated that, after the blister (38) is shaped, a non-pharmaceutical product including, but not limited to, a nutritional supplement, a vitamin, a foodstuff, and combinations thereof, may be disposed within the blister (38). Also, if the pharmaceutical product (48) is disposed within the blister (38), preferably there is a space defined by the blister (38) which allows the pharmaceutical product to move within the blister (38).

[0061] The pharmaceutical package (22) may also include a lacquer layer (40) disposed on the base layer (34) and sandwiching the base layer (34) between the lacquer layer (40) and the sealant layer (36). The lacquer layer (40) may be used as a surface for printing information on the pharmaceutical package (22). The lacquer layer (40) is preferably compatible with an ink used for printing to facilitate adhesion of the ink to the lacquer layer (40) resulting in decreased production costs of the pharmaceutical package (22). The lacquer layer (40) may include a tint. However, any lacquer layer known in the art may be used.

[0062] The pharmaceutical package (22) may also include an interior layer (42). The interior layer (42) may be disposed anywhere in the pharmaceutical package. However, in one embodiment, the interior layer (42) is preferably disposed between the lacquer layer (40) and the base layer (34). In another embodiment, the interior layer (42) is preferably disposed between the base layer (34) and the sealant layer (36). In yet another embodiment, the interior layer (42) is preferably disposed between the sealant layer (36) and the blister (38). It is to be understood that the pharmaceutical package (22) may also include second and third interior layers (44, 46). If the second and/or third interior layers (44, 46) are included, the second and/or third interior layers (44, 46) are preferably the same as the interior layer (42). However, the second and/or third interior layers (44, 46) may be different than the interior layer (42).

[0063] If included in the pharmaceutical package (22), the interior layer (42), in addition to the second and third interior layers (44, 46), preferably includes a material selected from the group of alcohols, polyamides, polyesters, polyolefins, polystyrenes, acrylics, polyurethanes, and combinations thereof. Suitable alcohols for use in the interior layer (42) include, but are not limited to, alkyl vinyl alcohols. Preferably, if the alcohol is used in the interior layer (42) the alcohol includes ethyl vinyl alcohol. Suitable polyamides for use in the interior layer (42) include, but are not limited to, polyamide homopolymers, copolymers, and combinations thereof.

[0064] Useful polyamide homopolymers include, but are not limited to, poly(4-aminobutyric acid) (nylon 4), poly(6-aminohexanoic acid) (nylon 6, also known as poly(caprolactam)), poly(7-aminoheptanoic acid) (nylon 7), poly(8-aminoctanoic acid)(nylon 8), poly(9-aminononanoic acid) (nylon 9), poly(10-aminodecanoic acid) (nylon 10), poly(11-aminoundecanoic acid) (nylon 11), poly(12-aminododecanoic acid) (nylon 12). Useful polyamide copolymers include nylon 4,6, poly(hexamethylene adipamide) (nylon 6,6), poly(hexamethylene sebacamide) (nylon 6,10),

poly(heptamethylene pimelamide) (nylon 7,7), poly(octamethylene suberamide) (nylon 8,8), poly(hexamethylene azelamide) (nylon 6,9), poly(nonamethylene azelamide) (nylon 9,9), poly(decamethylene azelamide) (nylon 10,9), poly(tetramethylenediamine-co-oxalic acid) (nylon 4,2), the polyamide of n-dodecanedioic acid and hexamethylenediamine (nylon 6,12), the polyamide of dodecamethylenediamine and n-dodecanedioic acid (nylon 12,12) and combinations thereof.

[0065] Useful polyamide copolymers include caprolactam/hexamethylene adipamide copolymer (nylon 6,6/6), hexamethylene adipamide/caprolactam copolymer (nylon 6/6,6), trimethylene adipamide/hexamethylene azelaiamide copolymer (nylon trimethyl 6,2/6,2), hexamethylene adipamide-hexamethylene-azelaiamide caprolactam copolymer (nylon 6,6/6,9/6), poly(tetramethylenediamine-co-isophthalic acid) (nylon 4,I), polyhexamethylene isophthalamide (nylon 6,I), hexamethylene adipamide/hexamethylene-isophthalamide (nylon 6,6/61), hexamethylene adipamide/hexamethyleneterephthalamide (nylon 6,6/6T), poly (2,2,2-trimethylhexamethylene terephthalamide), poly(m-xylylene adipamide) (MXD6), poly(p-xylylene adipamide), poly(hexamethylene terephthalamide), poly(dodecamethylene terephthalamide), polyamide 6T/6I, polyamide 6/MXDT/I, polyamide MXDI, and combinations thereof.

[0066] Non-limiting examples of suitable polyolefins include, but are not limited to, low density polyethylenes, linear low density polyethylenes, linear medium density polyethylenes, linear very-low density polyethylenes, linear ultra-low density polyethylenes, high density polyethylenes, metallocenes, and combinations thereof. Other suitable polyolefins include, but are not limited to, polyethylenes, polypropylenes, polybutylenes, polybutene-1, polypentene-1, poly-3-methylbutene-1, poly-4-methylpentene-1, polyhexene, copolymers of polyolefins,

copolymers of olefins, and combinations thereof. Non-limiting examples of suitable polyesters for use in the interior layer (42) include, but are not limited to, polyethylene terephthalate, glycol modified polyethylene terephthalate, and combinations thereof.

[0067] Each of the layers of the pharmaceutical package (22) including the base layer (34), the sealant layer (36), the lacquer layer (40), the interior layers (42, 44, 46), and the blister (38) may optionally include one or more conventional additives whose uses are well known to those skilled in the art. The use of such additives may be desirable in enhancing formation of the pharmaceutical package (22). Examples of such additives include oxidative and thermal stabilizers, impact modifiers such as thermoplastic olefins, thermoplastic elastomers, styrene butadiene rubber, and combinations thereof, lubricants, release agents, flame-retarding agents, oxidation inhibitors, oxidation scavengers, neutralizers, antiblock agents, dyes, pigments and other coloring agents, ultraviolet light absorbers and stabilizers, organic or inorganic fillers including particulate and fibrous fillers, reinforcing agents, nucleators, plasticizers, waxes, hot melt adhesives, and combinations thereof. These additives may be used in any amount in any of the layers (34, 36, 40, 42, 44, 46) and in the blister (38) of the pharmaceutical package (22). Representative ultraviolet light stabilizers include, but are not limited to, various substituted resorcinols, salicylates, benzotriazole, benzophenones, and combinations thereof. Suitable lubricants and release agents include, but are not limited to, stearic acid, stearyl alcohol, and stearamides. Exemplary flame-retardants include, but are not limited to, organic halogenated compounds, including decabromodiphenyl ether, inorganic compounds, and combinations thereof. Suitable coloring agents including dyes and pigments include, but are not limited to, cadmium sulfide, cadmium selenide, titanium dioxide, phthalocyanines, ultramarine blue, nigrosine, carbon black and combinations thereof. Representative oxidative and thermal

stabilizers include, but are not limited to, metal halides, such as sodium halides, potassium halides, lithium halides, cuprous halides, as well as corresponding chlorides, bromides, and iodides, respectively, and combinations thereof. Also, hindered phenols, hydroquinones, aromatic amines, and combinations thereof may be included. Exemplary plasticizers include, but are not limited to, lactams such as caprolactam and lauryl lactam, sulfonamides such as *ortho*- and *para*-toluenesulfonamide and N-ethyl, N-butyl benylsulfonamide, and combinations thereof, as well as other plasticizers known in the art.

[0068] The pharmaceutical package (22) may be assembled via a variety of means. In one embodiment of the present invention, the base layer (34), sealant layer (36), and blister (38) are attached by heat-sealing under heat and pressure. Heat-sealing techniques are well known in the art. Typically, the base and sealant layers (34, 36) and the blister (38) are heat sealed by disposing the individual base and sealant layers (34, 36) and the blister (38) on one another under conditions of sufficient heat and pressure to cause the base and sealant layers (34, 36) and the blister (38) of the pharmaceutical package (22) to combine into a unitary structure. Typically the base and sealant layers (34, 36) and the blister (38) are disposed on one another and pressed together by techniques well known in the art. The heat sealing is preferably performed at temperatures of from 120 to 175, more preferably of from 130 to 175, and most preferably of from 150 to 175, °C. Once the base and sealant layers (34, 36) and the blister (38) are combined into the unitary structure, the pharmaceutical package (22) is complete.

[0069] Once complete, the film (20) used to form blister (38) of the pharmaceutical package (22) preferably has a water vapor transmission rate of from 0.20 to 5.00, more preferably of from 0.20 to 3.00, and most preferably of from 0.20 to 0.50, g/m²/24 hrs, as determined by ASTM F-1249. Preferably, the film (20) also has a light transmission of from 88 to 93, and most preferably of

from 90 to 93, percent, as determined by ASTM D-1003. Further, the film (20) also preferably has a haze of from 2 to 9, more preferably of from 2 to 6, and most preferably of from 2 to 4, percent, also determined by ASTM D-1003.

EXAMPLES

[0070] The film (20) of the present invention can be used in conjunction with the pharmaceutical package (22) to form a seal and protect a content of the pharmaceutical package (22) from dust and/or moisture. The film (20) is created via a simultaneous extrusion of first, second, and third layers (24, 26, 28) of the film (20).

[0071] The first and third layers are simultaneously extruded from the first extruder including four temperature zones, including a first temperature zone, a second temperature zone, a third temperature zone, and a fourth temperature zone. The styrene butadiene copolymer of the first and third layers passes through the four temperature zones sequentially. The first temperature zone is maintained at a temperature of 177°C. The second temperature zone is maintained at a temperature of 195°C. The third temperature zone is maintained at a temperature of 210°C. The fourth temperature zone is maintained at a temperature of 215°C. After the styrene butadiene copolymer passes through the fourth temperature zone, the styrene butadiene copolymer exits the first extruder at a temperature of 219°C.

[0072] The second layer is extruded from the second extruder at the same time as the first and third layers are extruded from the first extruder. The second extruder, like the first extruder, includes four temperature zones, including a first temperature zone, a second temperature zone, a third temperature zone, and a fourth temperature zone. The cyclic olefin of the second layer also passes through the four temperature zones sequentially. The first temperature zone is maintained at a temperature of 247°C. The second temperature zone is maintained at a temperature of

253°C. The third temperature zone is maintained at a temperature of 240°C. The fourth temperature zone is maintained at a temperature of 240°C. After the cyclic olefin passes through the fourth temperature zone, the cyclic olefin exits the second extruder at a temperature of 266°C.

[0073] The film (20) is tested and physical properties of the film (20) such as Water Vapor Transmission Rate, Light Transmission, Haze, and Peel Strength are determined by ASTM test methods. Other physical properties such as Thickness and Density are also determined. The Light Transmission and Haze are set forth in Table 1 as an average measurement of five samples of the film (20). The Water Vapor Transmission Rate is set forth in Table 1 as an average measurement of two samples of the film (20). The Density is set forth in Table 1 as a measurement of one sample of the film (20).

[0074] The physical properties of the first, second, and third layers (24, 26, 28) of the film (20) are also determined by ASTM test methods. These physical properties include all of the physical properties described above except Peel Strength. The first and third layers (24, 28) of the film (20) including styrene butadiene copolymer are tested separately from the second layer (26) including a cyclic olefin copolymer. The Light Transmission and Haze are set forth in Table 2 as an average measurement of five samples of the first, second, and third layers (24, 26, 28) of the film (20). The Water Vapor Transmission Rate is set forth in Table 2 as an average measurement of two samples of the first, second, and third layers (24, 26, 28) of the film (20). The Density is set forth in Table 2 as a measurement of one sample of the first, second, and third layers (24, 26, 28) of the film (20).

[0075] Further, the physical properties of comparative films including polymers formed from halogenated molecules are determined by ASTM test methods. These physical properties also

include Water Vapor Transmission Rate, Light Transmission, Haze, and Peel Strength. The Comparative Example 1 Film includes a film having a single layer including polyvinyl chloride. The Comparative Example 2 Film includes a film having three layers including polyvinylidene chloride, polyethylene, and polyvinyl chloride. The Comparative Example 3 Film includes a film having two layers including polychlorotrifluoroethylene and polyvinylchloride. Specific physical properties of the Comparative Examples 1, 2, and 3 are set forth in Table 3.

Table 1

| Physical Properties of Film | Test Method (ASTM) | Units | Example 1 Film | Example 2 Film | Example 3 Film |
|-------------------------------|--------------------|----------------------------|----------------|----------------|----------------|
| Thickness | N/A | mils | 11.8 | 11.8 | 11.8 |
| Density | N/A | g/cm ³ | 1.02 | 1.02 | 1.02 |
| Water Vapor Transmission Rate | F-1249 | g/m ² / 24 hrs. | 0.31 | 0.32 | 0.28 |
| Light Transmission | D-1003 | % | 93 | 93 | 93 |
| Haze | D-1003 | % | 2.2 | 2.9 | 2.4 |
| Peel Strength | D-903 | lbs./in. | 1.72 | 1.62 | 0.74 |
| Peak Peel Strength | D-903 | lbs./in. | 1.89 | 1.69 | 0.80 |
| Yield | N/A | m ² /kg | ~ 3.20 | ~ 3.20 | ~ 3.20 |

[0076] Example 1 Film is the film (20) of the present invention. The first and third layers (24, 28) of the film (20) in Example 1 are Styrolux[®] 684D, commercially available from BASF Corporation, as the styrene butadiene copolymer. The second layer (26) of the film (20) in Example 1 Film is Topas[®] 8007F-04, commercially available from Ticona of Florence, KY, as the cyclic olefin copolymer. The first, second, and third layers (24, 26, 28) of the film (20) are co-extruded using methods well known in the art.

[0077] Example 2 Film is also the film (20) of the present invention. The first and third layers (24, 28) of the film (20) in Example 2 are Styrolux[®] 3G33, commercially available from BASF

Corporation, as the styrene butadiene copolymer. The second layer (26) of the film (20) in Example 2 Film is Topas® 8007F-04, commercially available from Ticona of Florence, KY, as the cyclic olefin copolymer. The first, second, and third layers (24, 26, 28) of the film (20) in Example 2 are also co-extruded using methods well known in the art.

[0078] Example 3 is also a film (20) of the present invention. The first and third layers (24, 28) of the film (20) in Example 3 are Styrolux® 3G55, commercially available from BASF Corporation, as the styrene butadiene copolymer. The second layer (26) of the film (20) in Example 3 Film is Topas® 8007F-04, commercially available from Ticona of Florence, KY, as the cyclic olefin copolymer. The first, second, and third layers (24, 26, 28) of the film (20) in Example 3 are also co-extruded using methods well known in the art.

[0079] Water Vapor Transmission Rate is a measurement, determined by ASTM F-1249, of a rate of water vapor transmission through a flexible barrier material, i.e., the film (20) of the present invention. The method is applicable for use with a film up to 118 mils thick.

[0080] Light Transmission is a measurement, determined by ASTM D-1003, of an amount of light that passes through a sample, i.e., the film (20) of the present invention.

[0081] Haze is a measurement, determined by ASTM D-1003, of a scattering of light as it passes through a transparent material, i.e., the film (20) of the present invention.

[0082] Peel Strength is a measurement, determined by ASTM D-903, of an average amount of load per unit width that is required to pull apart a bonded surface, i.e., pull apart the film (20) of the present invention.

[0083] Peak Peel Strength is the highest value of the load measured per unit width.

[0084] Yield is an amount of film area available per 1 kilogram of material.

Table 2

| Physical Properties of the Layers of the Film | Test Method (ASTM) | Units | Styrene Butadiene Copolymer First/Third Layers | Styrene Butadiene Copolymer First/Third Layers | Styrene Butadiene Copolymer First/Third Layers |
|---|--------------------|----------------------------|--|--|--|
| Thickness | N/A | mils | 1 | 2 | 4 |
| Density | N/A | g/cm ³ | 1.01 | 1.01 | 1.01 |
| Water Vapor Transmission Rate | F-1249 | g/m ² / 24 hrs. | 47.4 | 25.2 | 12.5 |
| Light Transmission | D-1003 | % | 93 | 93 | 93 |
| Haze | D-1003 | % | 1.5 | 1.5 | 2.2 |
| Yield | N/A | m ² /kg | 39 | 19.5 | 9.7 |

Table 2 (cont)

| Physical Properties of the Layers of the Film | Test Method (ASTM) | Units | Styrene Butadiene Copolymer First/Third Layers | Cyclic Olefin Copolymer Second Layer |
|---|--------------------|----------------------------|--|--------------------------------------|
| Thickness | N/A | mils | 11 | 11 |
| Density | N/A | g/cm ³ | 1.01 | 1.01 |
| Water Vapor Transmission Rate | F-1249 | g/m ² / 24 hrs. | ~20 | 0.26 |
| Light Transmission | D-1003 | % | 92 | ~ 92 |
| Haze | D-1003 | % | 2.9 | ~ 0.4 |
| Yield | N/A | m ² /kg | 3.5 | 3.5 |

[0085] Styrene Butadiene Copolymer is preferably used in the first and third layers (24, 28) of the film (20). The Styrene Butadiene Copolymer 1 in Table 2 is Styrolux® 684D, commercially available from BASF Corporation.

[0086] Cyclic Olefin Copolymer may be used in the second layer (26) of the film (20). The Cyclic Olefin Copolymer in Table 2 is Topas® 8007F-04, commercially available from Ticona of Florence, KY.

Table 3

| Physical Properties of the Film | Test Method (ASTM) | Units | Comparative Example 1 Film | Comparative Example 2 Film | Comparative Example 3 Film |
|---------------------------------|--------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| Thickness | N/A | Mils | 11 | ~ 11.9 | 10.4 |
| Density | N/A | g/cm ³ | 1.38 | N/A | N/A |
| Water Vapor Transmission Rate | F-1249 | g/m ² / 24 hrs. | 2.85 | 0.30 | 0.39 |
| Light Transmission | D-1003 | % | 93 | ~ 90 | ~ 90 |
| Haze | D-1003 | % | 1.2 | N/A | N/A |
| Peel Strength | D-903 | lbs _f /in. | > 1.5 | > 1.5 | > 1.5 |
| Yield | N/A | m ² /kg | ~ 2.87 | ~ 2.17 | ~ 2.5 |

[0087] Comparative Example 1 Film is a film including a polymer formed from halogenated molecules. The film includes polyvinyl chloride, commercially available from Klöckner Pentaplast of America, Inc. of Gordonsville, VA, under the trade name of Pentapharm®, as a single layer. The film is manufactured by a calendaring process.

[0088] Comparative Example 2 Film is also a film including a polymer formed from halogenated molecules. The film includes polyvinylidene chloride coated onto polyethylene. The polyethylene is laminated onto polyvinyl chloride. The polyvinylidene chloride is commercially available from The Dow Chemical Company of Midland, MI, under the trade name of Saran®. The polyvinyl chloride is commercially available from Klöckner Pentaplast of America, Inc. of Gordonsville, VA, under the trade name of Pentapharm®.

[0089] Comparative Example 3 Film is also a film including a polymer formed from halogenated molecules. The film includes polychlorotrifluoroethylene, commercially available from Honeywell International Inc. of Morristown, NJ, under the trade name of ACLAR[®]Rx 160, laminated to polyvinyl chloride. The Comparative Example 3 Film is formed by an adhesive lamination process well known in the art.

[0090] Upon testing, it is determined that the water vapor transmission rate of the film (20) of the present invention is lower than the water vapor transmission rate of the film of Comparative Example 1 Film and comparable to the water vapor transmission rate of the films of Comparative Example Films 2 and 3 which include halogens such as chlorine and fluorine.

[0091] It is also determined that the light transmission of the film (20) of the present invention is comparable to the light transmission of the films of Comparative Example Films 1, 2, and 3.

[0092] The invention has been described in an illustrative manner, and it is to be understood that the terminology which has been used is intended to be in the nature of words of description rather than of limitation. Obviously, many modifications and variations of the present invention are possible in light of the above teachings, and the invention may be practiced otherwise than as specifically described.

CLAIMS

What is claimed is:

1. A film comprising:

a first layer comprising styrene butadiene copolymer;

a second layer comprising a cyclic olefin and disposed on said first layer; and

a third layer comprising styrene butadiene copolymer and disposed on said second layer as an outermost layer of said film,

wherein said first and third layers are substantially free of cyclic olefin and said second layer is substantially free of styrene butadiene copolymer.

2. A film as set forth in claim 1 wherein said film is substantially free of halogens.

3. A film as set forth in claim 1 wherein said first, second, and third layers are extruded simultaneously.

4. A film as set forth in claim 1 wherein said second layer is disposed in contact with said first layer.

5. A film as set forth in claim 4 wherein said third layer is disposed in contact with said second layer.

6. A film as set forth in claim 1 wherein said third layer is disposed in contact with said second layer.

7. A film as set forth in claim 1 further comprising an intermediate layer disposed between said first and second layers.

8. A film as set forth in claim 7 further comprising a second intermediate layer disposed between said second and third layers, wherein said second intermediate layer is the same as said intermediate layer.

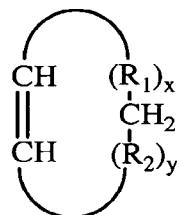
9. A film as set forth in claim 1 further comprising an intermediate layer disposed between said second and third layers.

10. A film as set forth in claim 1 wherein said styrene butadiene copolymer comprises the reaction product of:

a styrene monomer; and

1,3-butadiene.

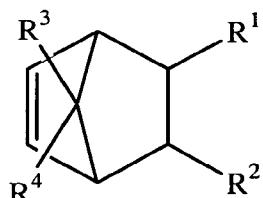
11. A film as set forth in claim 1 wherein said cyclic olefin comprises the general structure:



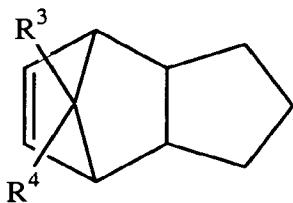
wherein each of R_1 and R_2 independently comprise one of a hydrogen and a hydrocarbon; and

wherein x and y independently comprise an integer less than or equal to 10.

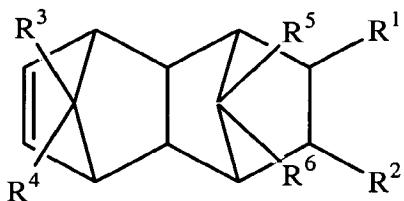
12. A film as set forth in claim 1 wherein said cyclic olefin is selected from one of the general structures:



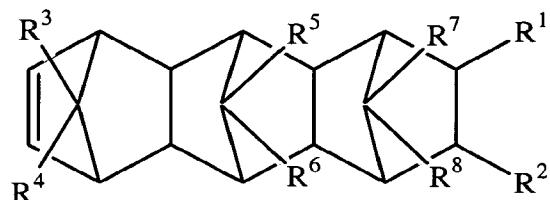
(I),



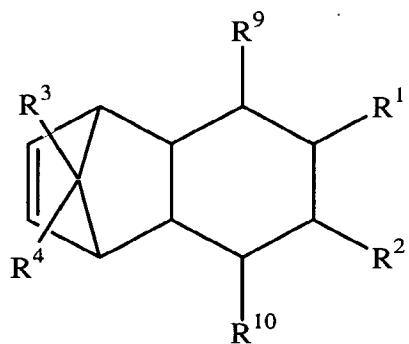
(II),



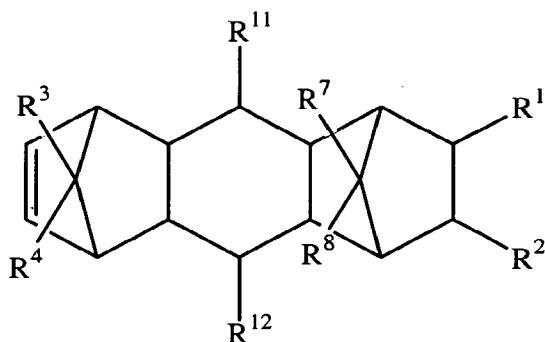
(III),



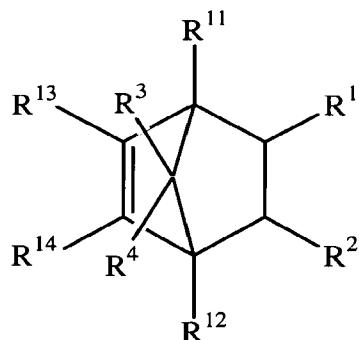
(IV),



(V),



(VI),



(VII),



(VIII),

wherein each of R¹ through R¹⁴ independently include one of an aryl group, and alkyl group, a halogen, and a hydrogen; and

wherein n includes an integer less than or equal to 10.

13. A film as set forth in claim 12 wherein said cyclic olefin comprises norbornene.
14. A film as set forth in claim 1 wherein said cyclic olefin comprises at least one pendant organic group.
15. A film as set forth in claim 1 wherein said cyclic olefin comprises a cyclic olefin copolymer.

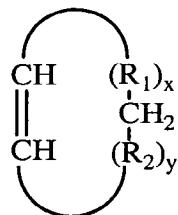
16. A film as set forth in claim 15 wherein said cyclic olefin copolymer comprises the interaction product of:

said cyclic olefin; and

a cross-linker.

17. A film as set forth in claim 16 wherein said cross-linker is selected from the group of alkanes, alkenes, alkynes, and combinations thereof.

18. A film as set forth in claim 15 wherein said cyclic olefin copolymer comprises the general structure:



wherein each of R_1 and R_2 independently comprise one of a hydrogen and a hydrocarbon; and

wherein x and y independently comprise an integer less than or equal to 10.

19. A film as set forth in claim 15 wherein said cyclic olefin copolymer comprises norbornene.

20. A film as set forth in claim 15 wherein said cyclic olefin copolymer comprises at least one pendant organic group.

21. A film as set forth in claim 1 wherein said film has a density of from 0.98 to 1.03 g/cm³.

22. A film as set forth in claim 1 wherein said film has a peel strength of greater than 1.0 lbs./in. as determined by ASTM D-903.

23. A film as set forth in claim 1 having a water vapor transmission rate of from 0.20 to 3.00 g/m²/ 24 hrs. as determined by ASTM F-1249.
24. A film as set forth in claim 1 having a light transmission of from 88 to 93 percent as determined by ASTM D-1003.
25. A film as set forth in claim 1 having a haze of from 2 to 6 percent as determined by ASTM D-1003.
26. A film as set forth in claim 1 wherein said first layer has a thickness of from 1 to 8 mils.
27. A film as set forth in claim 1 wherein said second layer has a thickness of from 3 to 8 mils.
28. A film as set forth in claim 1 wherein said third layer has a thickness of from 1 to 8 mils.

29. A pharmaceutical package comprising:

- a base layer;
- a sealant layer disposed on said base layer; and
- a blister disposed on said sealant layer and formed from a film comprising:
 - a first layer comprising styrene butadiene copolymer;
 - a second layer comprising a cyclic olefin and disposed on said first layer;

and

- a third layer comprising styrene butadiene copolymer and disposed on said second layer as an outermost layer of said film,

wherein said first layer and third layers are substantially free of cyclic olefin and said second layer is substantially free of styrene butadiene copolymer.

30. A pharmaceutical package as set forth in claim 29 further comprising a pharmaceutical product disposed within said blister.

31. A pharmaceutical package as set forth in claim 29 wherein said sealant layer is disposed in contact with said base layer.

32. A pharmaceutical package as set forth in claim 31 wherein said blister is disposed in contact with said sealant layer.

33. A pharmaceutical package as set forth in claim 29 wherein said blister is disposed in contact with said sealant layer.

34. A pharmaceutical package as set forth in claim 29 wherein said base layer comprises aluminum.

35. A pharmaceutical package as set forth in claim 29 further comprising a lacquer layer disposed on said base layer and sandwiching said base layer between said lacquer layer and said sealant layer.

36. A pharmaceutical package as set forth in claim 35 further comprising an interior layer disposed between said lacquer layer and said base layer.

37. A pharmaceutical package as set forth in claim 29 further comprising an interior layer disposed between said base layer and said sealant layer.

38. A pharmaceutical package as set forth in claim 29 further comprising an interior layer disposed between said sealant layer and said blister.

39. A pharmaceutical package as set forth in claim 29 wherein said film has a water vapor transmission rate of from 0.20 to 3.00 g/m²/ 24 hrs. as determined by ASTM F-1249.

40. A pharmaceutical package as set forth in claim 29 wherein said film has a light transmission of from 88 to 93 percent as determined by ASTM D-1003.

41. A pharmaceutical package as set forth in claim 29 wherein said film has a haze of from 2 to 6 percent as determined by ASTM D-1003.

42. A method of making a film, said method comprising the steps of:
 - a) forming a first layer comprising styrene butadiene copolymer;
 - b) forming a second layer comprising a cyclic olefin on the first layer; and
 - c) forming a third layer comprising styrene butadiene copolymer on the second layer

as an outermost layer of the film,

wherein the first and third layers are substantially free of the cyclic olefin and the second layer is substantially free of styrene butadiene copolymer.

43. A method as set forth in claim 42 wherein the step of forming the first layer comprises extruding the first layer, the step of forming the second layer comprises extruding the second layer, and the step of forming the third layer comprises extruding the third layer.

44. A method as set forth in claim 43 wherein the first, second, and third layers are simultaneously extruded.

45. A method as set forth in claim 42 further comprising the step of melt-bonding the first, second, and third layers.

46. A method as set forth in claim 42 wherein the film is substantially free of halogens.

47. A method as set forth in claim 42 wherein the second layer is formed in contact with the first layer.

48. A method as set forth in claim 47 wherein the third layer is formed in contact with the second layer.

49. A method as set forth in claim 42 wherein the third layer is formed in contact with the second layer.

A MULTI-LAYERED FILM FOR PACKAGING

ABSTRACT OF THE DISCLOSURE

A multi-layered film can be used to form a blister in a package. The film includes a first layer that includes styrene butadiene copolymer. The film also includes a second layer, disposed on the first layer, that includes a cyclic olefin. The film further includes a third layer, disposed on the second layer, as an outermost layer of the film. The third layer also includes styrene butadiene copolymer. The first, second, and third layers can be used in a method of forming the multi-layered film. The styrene butadiene copolymer allows the film to be substantially transparent, impact resistant, and thermoformable resulting in a low cost of producing the film. The styrene butadiene copolymer also allows the film to have a low density. The cyclic olefin substantially prevents moisture from passing through the film.

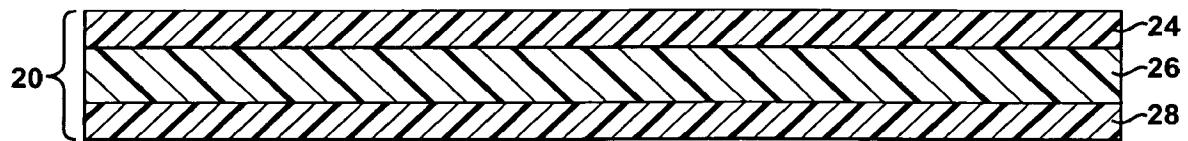


FIG - 1

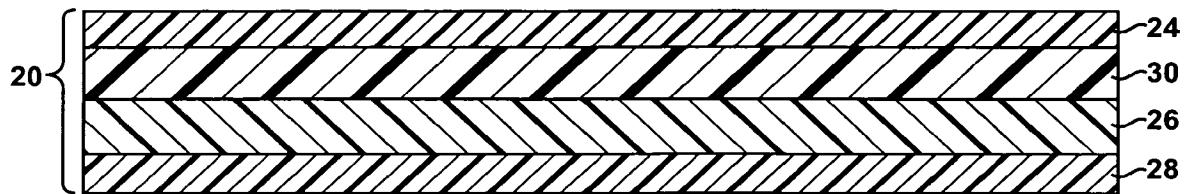


FIG - 2

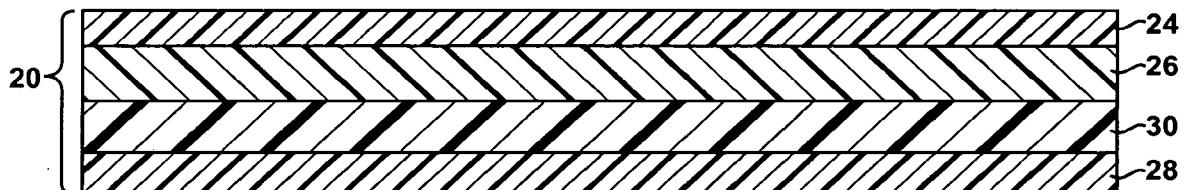


FIG - 3

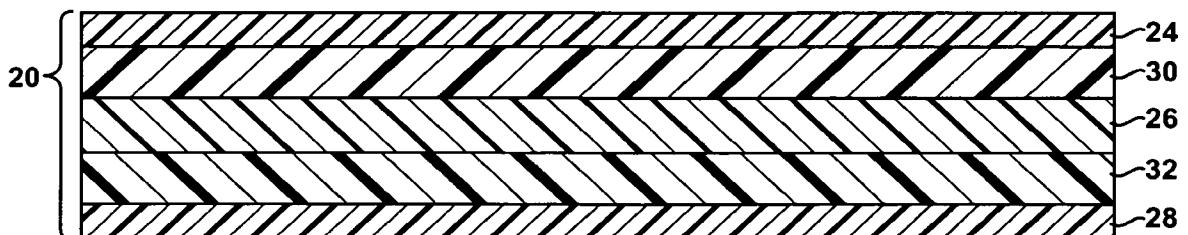


FIG - 4

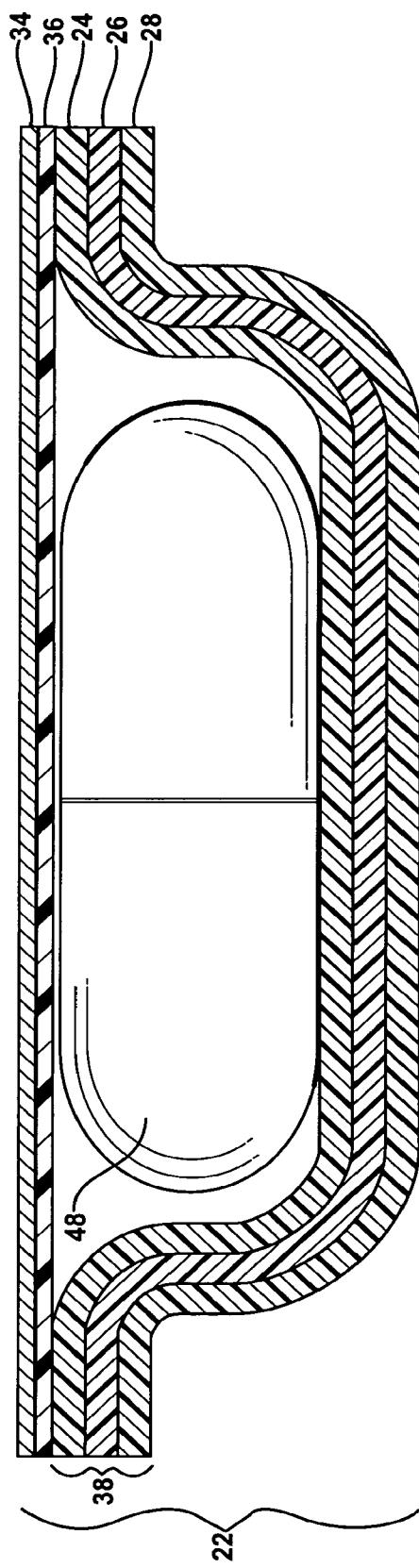


FIG - 5

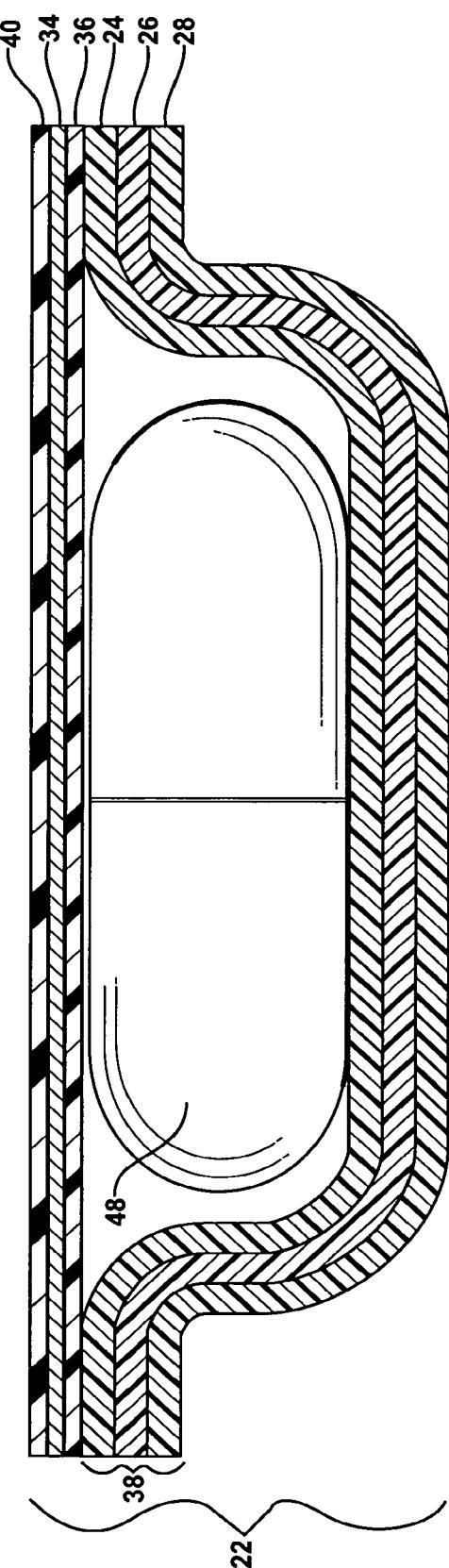


FIG - 6

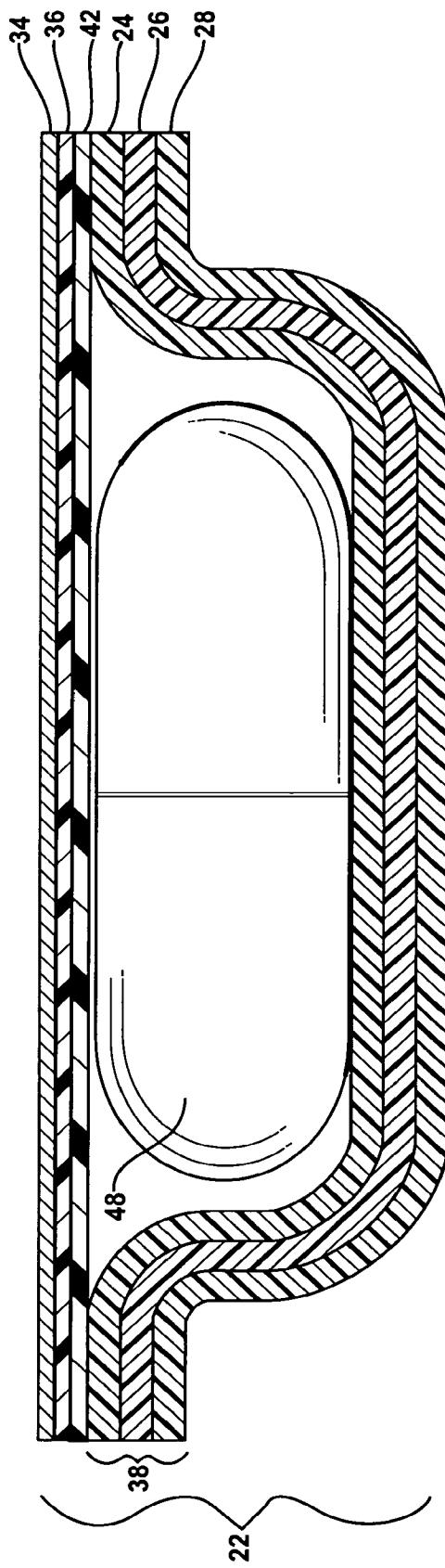


FIG - 7

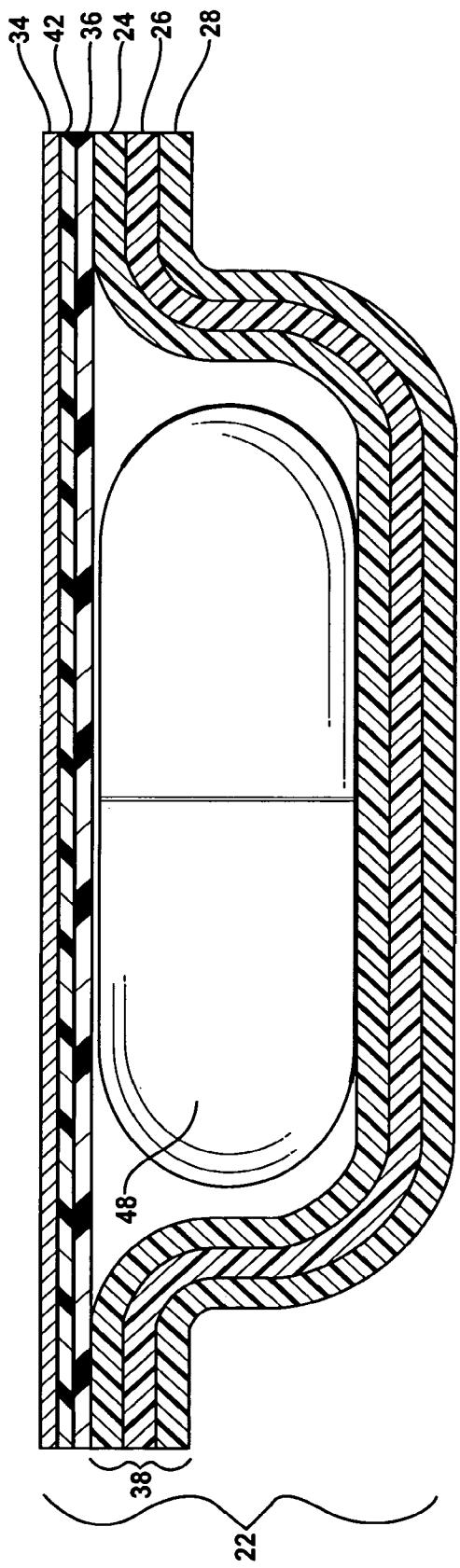


FIG - 8

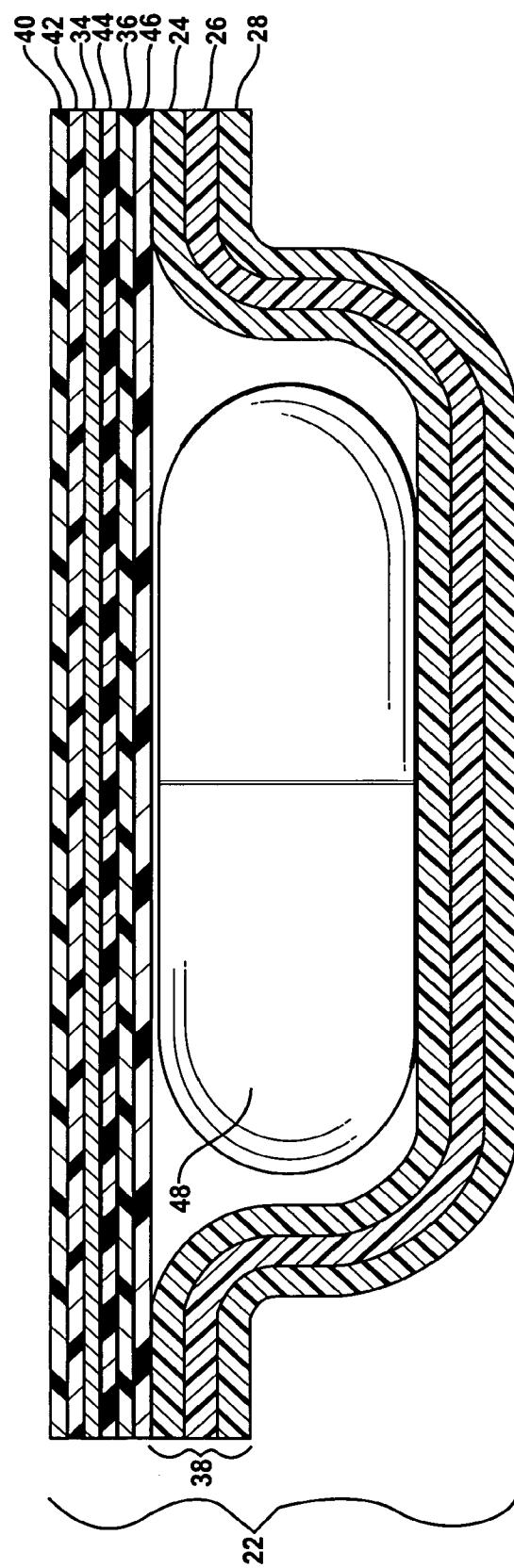


FIG - 9